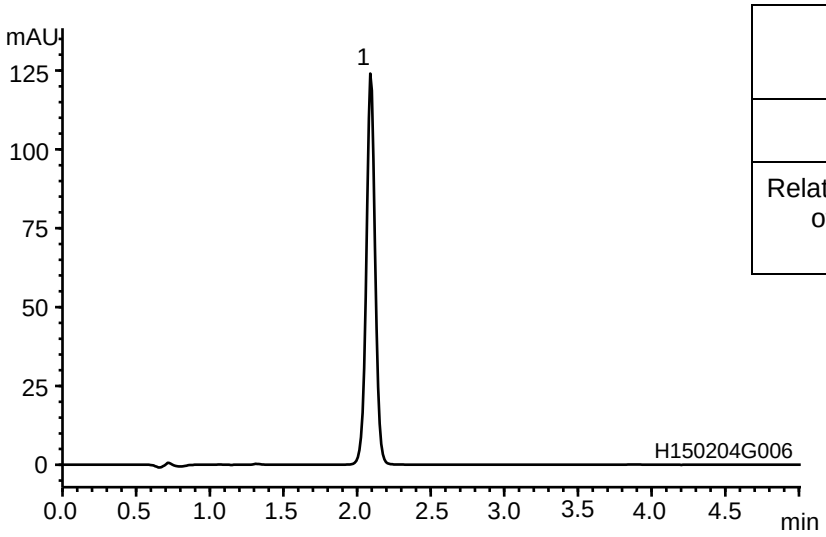
HPLC DATA SHEET

モンテルカストナトリウム顆粒（米国薬局方原案記載条件）
Montelukast sodium oral granules　(The draft for The United States Pharmacopoeia)

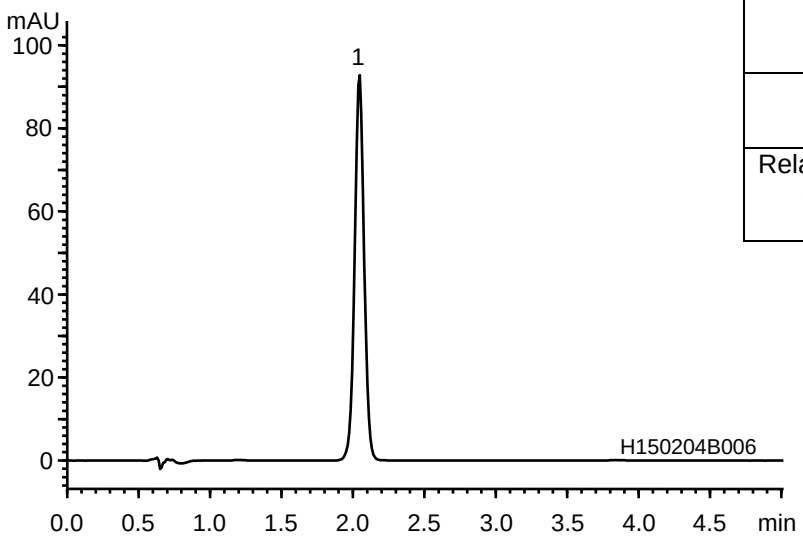
H150501C

(A) Dissolution: Standard solution
(4.4 µg/mL Montelukast)

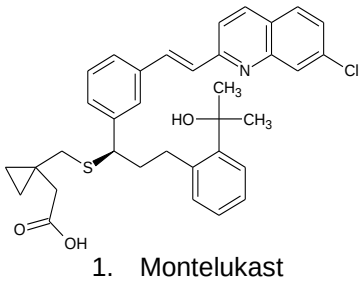


	System suitability requirement	Result
Tailing factor (Montelukast)	≦1.5	1.08
Relative standard devition of peak area (n=5) (Montelukast)	≦2.0%	0.12%

(B) Uniformity of dosage units: Standard solution
(0.020 mg/mL Montelukast)



	System suitability requirement	Result
Tailing factor (Montelukast)	≦1.5	1.09
Relative standard devition of peak area (n=5) (Montelukast)	≦2.0%	0.15%



1.　Montelukast

Column	: YMC-Pack Ph (5 µm, 12 nm) 100 X 3.0 mmI.D.
Eluent	: acetonitrile/water/TFA (500/500/2)
Flow rate	: 0.9 mL/min
Temperature	: 50℃
Detection	: UV at 389 nm
Injection	: A) 25 µL, B) 5 µL

(The draft for The United States Pharmacopoeia 40th; Dissolution, Uniformity of dosage units)

*All Standard solutions were prepared from Montelukast sodium salt hydrate supplied as a reagent for laboratory use.